

**General License Relating to Certain
Measuring, Gauging or Controlling Devices**

The following information is being provided by the State of Wisconsin, Department of Health and Family Services (DHFS), Radiation Protection Section is a summary of *s. HFS 157.11 (2) (b)*, to be used by the registrant in order to understand the requirements that pertain to “General License Relating to Certain Measuring, Gauging or Controlling Devices.”

s. HFS 157.11 (2) (b)

(b) General license relating to certain measuring, gauging or controlling devices.

1. A general license is issued to commercial and industrial firms and to research, educational and medical institutions, individuals in the conduct of their business and state or local government agencies to own, receive, acquire, possess, use or transfer under the provisions of sections 2., 3., 4., and 5., of this summary, radioactive material, excluding special nuclear material, contained in devices designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage or qualitative or quantitative chemical composition or for producing light or an ionized atmosphere.
2. The general license issued under this paragraph applies only to radioactive material contained in devices that have been manufactured and labeled under the specifications contained in a specific license issued by the department under *s. HFS 157.13 (4) (d)* or under the specifications contained in a specific license issued by the NRC, an agreement state or a licensing state, which authorizes distribution of devices to persons generally licensed by the NRC, an agreement state or a licensing state.

Note: Regulations under the Federal Food, Drug and Cosmetic Act authorizing the use of radioactive control devices in food production require certain additional labeling thereon which is found in *21 CFR 179.21*.

3. A person who owns, receives, acquires, possesses, uses or transfers radioactive material in a device under the general license under this paragraph shall do all of the following:
 - a. Ensure that all labels affixed to the device at the time of receipt and bearing a statement that removal of the label is prohibited, are maintained and shall comply with all instructions and precautions provided by such labels.
 - b. Ensure that the device is tested for leakage of radioactive material and proper operation of the “on-off” mechanism and indicator, if any, at no longer than 6-month intervals or at such other intervals as are specified in the label, except for devices containing only krypton, tritium, not more than 3.7 MBq (100 microcuries) of other beta and gamma-emitting material, or 0.37 MBq (10 microcuries) of alpha-emitting material, and devices held in storage in the original shipping container prior to initial installation.
 - c. Ensure that other testing, installation, servicing and removal from installation involving the radioactive material, its shielding or containment, are performed under the instructions provided by the labels, or by a person holding an applicable specific license from the department, the NRC, an agreement state or licensing state to perform such activities.

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- d. Maintain records showing compliance with the requirements of paragraphs 3 b. and c. of this summary. The records shall show the results of tests. The records shall also show the dates of performance of tests, and the names of persons performing testing, installation, servicing and removal from installation of the radioactive material, its shielding or containment. Records of tests for leakage of radioactive material required by paragraph 3.b shall be maintained for 3 years or until the sealed source is transferred or disposed of. Records of tests of the “on-off” mechanism and indicator required by paragraph 3.b shall be maintained for 3 years or until the sealed source is transferred or disposed of. Records that are required by paragraph 3.c shall be maintained for a period of 3 years from the date of the recorded event or until the device is transferred or disposed of.
 - e. Upon the occurrence of a failure or damage to, or any indication of a possible failure of or damage to, the shielding of the radioactive material or the “on-off” mechanism or indicator, or upon detection of 185 Bq (0.005 microcurie) or more removable radioactive material, shall immediately suspend operation of the device until it has been repaired by the manufacturer or other person holding an applicable specific license from the department, the NRC, an agreement state or a licensing state to repair such devices, or disposed of by transfer to a person authorized by an applicable specific license to receive the radioactive material contained in the device. The licensee shall file a written report containing a brief description with the department within 30 days of the event.
 - f. Not abandon the device containing radioactive material.
 - g. Except as provided in paragraph 3.h of this summary, transfer or dispose of the device containing radioactive material only by transfer to a specific licensee of the department, the NRC, an agreement state or a licensing state whose specific license authorizes that person to receive the device and within 30 calendar days after transfer of a device to a specific licensee shall furnish to the department a written report containing identification of the device by manufacturer’s name, model number and serial number and the name and address of the person receiving the device. No report is required if the device is transferred to the specific licensee to obtain a replacement device.
 - h. Transfer the device to another general licensee only where the device is held in storage in the original shipping container at its intended location of use prior to initial use by a general licensee, or where the device remains in use at a particular location. In the latter case, the transferor shall give the transferee a copy of regulations in this summary, and any safety documents identified in the label on the device and within 30 calendar days of the transfer. The licensee shall report to the department the manufacturer’s name and model number of device transferred, the name and address of the transferee, and the name and position of an individual who may constitute a point of contact between the department and the transferee.
 - i. Comply with the provisions of s. *HFS 15.32 (1) and (2)* for reporting radiation incidents, theft or loss of licensed material, but shall be exempt from the other requirements of *subchapters III and X of Chapter HFS 157*.
4. The general license under this paragraph does not authorize the manufacture of devices containing radioactive material.
 5. The general license under this paragraph is exempt from the requirements of *subchapter III of Chapter HFS 157*, with the exception of s. *HFS 157.30 (1), 157.32 (1) and (2)* and *subchapter X of Chapter HFS 157*.

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